Report of the ACvA/Industry Roundtable
17 March 2020

Introduction

The ACvA Industry Roundtable was held on 17 March 2020, following two roundtables in 2019, including a major brainstorming session with the MedTech Actuator in Melbourne.

Responding to the escalating COVID-19 situation, we moved quickly from the proposed face to face meeting to a virtual meeting. We were very pleased to secure participation of the majority of our original speakers and to have Kieran Schneemann, Director Government Affairs, AstraZeneca and Director of Canteen, to facilitate the meeting.

Background

The core purpose of the March roundtable was to continue to build a strong platform of engagement between industry and the research community to tackle Australia's biggest health burden, drive economic outcomes and agree on the establishment of two focused working groups to move a shared agenda forward. The two working groups will be focused on the following tasks, respectively:

1. Accelerating the delivery of evidence-based and value-based care driving equitable health outcomes for all Australians.
2. Implementing a new vision for industry/academic partnership, capturing our research and innovation potential for commercial, economic and patient outcomes.

Roundtable – Discussion and Outcomes

SESSION ONE: ACvA's Vision and Strategy- and the key role of our Industry Partner

- Professor Kerry-Ann Rye (Chair of the ACvA Industry and Commercialisation Committee) started the meeting with a call to action, asking that we come to a clear definition of the issues we are seeking to address and to commit to structured partnerships to drive to solutions.
- Professor Gemma Figtree (President of the ACvA) described how the ACvA has evolved, bringing on board operational staff and increasing its focus and momentum in supporting the translation of research and embedment into our health care system. The ACvA is helping to break down silos, coordinate cross-jurisdictional/cross-disciplinary work, forge new partnerships and provide a platform for relationships to deepen. The ACvA Flagship operational team is now set up - with honorary directors and 10 advisory group members for each flagship. The ACvA's goal is to make

Australia the global destination for all levels of industry and academic collaboration, with ACvA providing a one stop shop for engagement, communication, collaboration and scale up.

SESSION TWO: Accelerating delivery of evidence-based and value-based care for optimal CV health for all Australians

The consumer perspective (Kieran Schneemann and Rebecca Davies)

The consumer voice has evolved significantly. When consumer involvement in research was first raised 20 or so years ago, many in the research community were perplexed as to what benefits their involvement might bring. Now the consumer perspective is seen as essential to define problems, incentivise solutions, promote the benefits of research and ensure the relevance of outcomes.

Rebecca Davies noted that in a recent MRFF process, her voice was heard across the review of all grant applications and her views considered strategically. Kieran Schneemann stressed that consumers alongside researchers can be a very powerful and influential voice to Government, other key influencers and decision makers. Cancer has done this well and it may be one of the key reasons they receive more research funding.

Government and Pharmaceutical Benefits Advisory Committee (PBAC) perspective (Professor Andrew Wilson)

- PBAC roles and functions are clearly defined in legislation.
- PBAC is the main, though not the only (85%) "funder" of pharmaceuticals in the community.
- Medicines tend to be for use in hospitals and PBAC is also responsible for safety monitoring of drugs and the comparative nature of this role in registrations is important.
- PBAC has limited remit in relation to mechanisms to support innovation. This may be something for the future.
- PBAC receives requests to endorse or support clinical trials but currently has limited capacity to do this, making recommendations to Government on an ad hoc basis as time allows.
- The question of how we "perform" in getting evidence-based medicine through PBAC and to patients versus other disease sectors was discussed from a research, innovation, industry and consumer perspective. It was noted that we do not have a coordinated approach to this- and that most effort comes from small groups with interest in areas related to a specific drug. The benefits of establishing an advisory board with diverse perspectives to help prioritise and advocate for new medicines was discussed.

Medical Services Advisory Committee (MSAC) and clinical perspectives (Professor John Atherton)

- MSAC is an independent non-statutory committee established by the Australian Government in 1998.
- MSAC appraises new medical services proposed for public funding and provides advice to the Federal Government on whether a new medical service should be publicly funded following an assessment of its comparative safety, clinical effectiveness, cost-effectiveness and total cost, using the best available evidence.
    - MSAC also advises the Australian Health Ministers' Advisory Council on health technology assessments referred under AHMAC arrangements.
    - It is important to note that there is no obligation on Government to accept or implement the advice MSAC provides, though it is unusual for them not to do so. Coordination and

prioritisation of new applications by a diverse group from the CV sector is not currently formalised.

- Applications to MSAC can be made by the medical profession, medical industry and others, including health care professionals.
- The MSAC process has two stages:
  - Pre-assessment stage: Approx. 20 weeks
    - Triage: The Department verifies the availability of evidence, determines suitability for MSAC consideration and undertakes targeted public consultation.
    - Population Intervention Comparator Outcome (PICO) Confirmation: PICO Confirmation is developed by a Health Technology Assessment Group, including clinical algorithms.
  - Assessment stage: Approx. 22 weeks
    - Application Assessment: Evidence outlined in the PICO confirmation is presented in an Assessment report and reviewed to identify the gaps and levels of uncertainty in the evidence.
    - Appraisal: MSAC appraises the evidence before advising Government. Consideration includes the assessment report, the independent critique, the Evaluation Sub-Committee report, feedback from the applicant/other relevant parties, and the individual expertise of MSAC members.
    - MSAC's advice to the Minister is made public on the MSAC website via a Public Summary Document.
    - The real-world impacts of MSAC-supported applications are assessed by comparing projections of claims with actual service volume patterns approximately 24 months after listing.
  - Discussion centred on the need to take a whole of sector approach to assess patient benefit, citing MRI services as an example. It was noted that genomics has an implementation working group bringing together all areas and agreeing how to advocate specific items for consideration. GF briefly described the Genomics Implementation Advisory Group, which has formal mechanisms to enable diverse views to contribute to the prioritisation of diagnostics and medical innovations and medical services, with State, Federal, MSAC. PBAC representation at the table.

Challenges in Pharma (Professor Carol Pollock)

In considering how to engage with Pharma, we should:

- Proactively consider industry pipelines and identify gaps.
- Proactively seek out industry contacts.
- Better understand the challenges and limitations within which pharma is working, including finite funding and resources.
- Be ruthlessly honest in identifying and valuing our own skills respective to those of our proposed partners. For example, economic analysis and commercialisation are often best left with the industry partner rather than the scientist.
- Consider a range of partners and models. Big pharma is thought of as the obvious partner, however, in many cases, smaller biotechs may be more open to partnering, as they may not have the full skill-set internally required to push forward down the commercialization pathway.
- Partnering with a local biotech/SME that then partners with a big Pharma company can be a better model than always seeking to immediately partner with Pharma.

- Acknowledge that the tech transfer offices in the University sector are not well developed in respect of working with the hospital sector.
- Consider more open and flexible approaches to IP. Institutions often expect to own the IP which can stymie progress, putting discoveries in the too hard basket/leaving potential important IP on the shelf.
- Consider when contract research may be a more acceptable pathway to short term outcomes, long term partnerships, knowledge development and skills transfer.
- Where feasible, seek philanthropic or seed funding to make the partnership more attractive or feasible to industry.
- Consider creative ways to build relationships, for example, partners may want the use of an animal facility - not necessarily for your product. Acting as a facilitator or broker will enhance your reputation and build trust.
- Better capitalise on the fact that the health sector does a substantial amount of inexpensive beta testing for new technology.

Key areas recommended for focus are:

- Addressing the challenge of finding sufficient numbers of consumers for review panels.
- Investing in training to upskill consumer in the research process.
- Acknowledging the altruistic nature of consumer involvement, the time and commitment required to participate and, explore reimbursement of expenses at the very least and/or perhaps payment to show the value and importance of the consumer voice.
- Harnessing the consumer voice for more powerful advocacy impact.
- Embedding big data and health economics.
- Mapping Australian pathways and processes and comparing to international best practice.
- Establishing an Implementation Group, based on the Genomics model.
- Developing "point people" in state and federal health departments to contribute to the Implementation Group, as well as support implementation in relevant jurisdictions.
- Identifying risks and mitigation approaches.
- Build coordinated capacity in health economics and impact assessment, to strive towards value-based care.
- Identifying feasible areas for advocacy.
- Mapping the various pathways for increasing engagement with industry.
- Building trust in the sector, including industry - "one voice" with transparent processes can help accelerate implementation of broad range of value-based medicine and device therapy.
- Creating opportunities, such as the proposed working groups for understanding each other's drivers and priorities and developing a shared language

SESSION THREE: A new vision for Australian CV industry/academic partnerships

Health and economic drivers for building sustainable industry academic partnerships in the CV space (Ms Anita Van Der Meer – Manager of Clinical Trials NSW)

- Health and Medical research is a business and the ACvA has a key role to play in assisting the sector to capitalise on this business.

- Public research and development investment has increased - up to $1.5 billion but this is not enough on its own. Now is the time for stronger collaboration to ensure new innovations to our healthcare system.
- In AU approx. 5000 patients are involved in trials and there were about 2500 different trials in 2018 > 50% of which were industry funded.
- A recent comprehensive analysis of clinical trials has been undertaken to determine gaps and partnership opportunities to drive growth in the clinical trials sector. It is clear that academic/industry collaboration drives the development of innovative solutions and creates research pull through that further develops and matures our research sector.
- We need to take a long term/sustainability approach - with appropriate and careful financial management there is a possibility to create a return on investment that can fund future work.
- With the leadership, coordination and collaborative potential provided by the ACvA, it may be possible to focus on creating this ecosystem in the CV area, looking for strengths, gaps and opportunities, mapping current funding sources and identifying which of these can be capitalised on.

Australia as the "go to" destination for large scale clinical trials (Dr. Clare Arnott)

Challenges and opportunities include:

- Lack of existing infrastructure is a major issue which leads to inefficiency, delays, cost and effects study feasibility. Timelines often blow out due to the need to hire staff, obtain lengthy ethics approvals etc once you do attract funding. This is particularly relevant in peer reviewed funding due to the tight timelines.
- Research indicates that 56% of Australians are willing to be involved in trials but far less are.
- We are generally poor in Australian at recruitment, especially through General Practice as there is no national infrastructure in place. This leads to high cost and low yield for industry to invest in.
- The Scottish SHARE registry is a significant model which can be replicated. We are looking at to develop a nationwide, disease-agnostic register in Australia. The Scottish SHARE register is an efficient, cost-effective opt-in system, which operates at <$1 per recruit. Challenges to taking this project forward locally include:
    - The need for significant collaboration as there are individual registries, often disease specific, and competing personal interests.
    - The need for strong and structured collaboration from industry and Governments.
    - Ensuring this activity is consumer led and that we are held accountable to the consumer.
- Creating the necessary research infrastructure within health districts, so when money is available, we are ready to go.

Building a national showcase and "one front door" to facilitate industry engagement at early stages of discovery and innovation (Professor John Fraser)

- Lack of a shared language, drivers and vision underpin gaps in industry engagement. For example, industry works faster than scientists, they want 99% completion fast, rather than 100% over a longer time period.
- Each sector has a different set of rules and brings very different value propositions to the partnership table.
- Academia needs to understand and articulate its value, for example the strong community reputation that researchers and clinicians enjoy can be associated with attracting patients, adhering to strict ethical standards and achieving tangible health outcomes.

- Academia needs to be clear what it wants, what it will achieve and what is required to get there, particularly when look for funding partners – and especially in approaching governments for support.

Industry/academic partnerships in advancing CV imaging – who does it well and opportunities in Australia (Prof. Stuart Grieve)

- Translation is not generally done well in Australia.
- Clinical and fundamental and research imaging is, however, thought of very highly in Australia.
- Historically most relationships with industry have been through pockets of excellence that vendors look to and some regionally significant institutional relationships, however, it tends to be equipment focused and very sales oriented.
- We need to focus on assets and building coordinated world-class platforms based on our strengths and excellent health care system: systems and access to patients; secure data platforms and coordinated ethics/governance for handling of nation-wide large imaging data sets for registry (quality assurance) and research purposes; good methods for accessing and analysing data; and relationships with vendors who sell equipment; and we should build up partnerships with non-imaging vendors such as Genesis Healthcare.
- Deploying capability is a current issue.
- Radiologists are very busy, business goes up 10% a year and margins go down, there is little time for strategic thinking and planning.
- Creating opportunities - developing scale through partnerships and collaboration should be prioritised.

Promoting the ACvA and the Australian CV research sector to our global research leads – working together to build a world-leading translational research eco-system (Mr. John Crothers Abbott)

- The ACvA demonstrates the power of one – a critical asset in a relatively small and somewhat fragmented market.
- We need to develop a strong unique value proposition to overcome the challenges of geography, time-zone and relationships.
- We must understand industry drivers. There is an opportunity for industry and research to better understand each other and respectfully find a common language.
- Key partner criteria assessment that multi-national corporations like Abbott consider:
  - Is it strategically aligned?
  - Degree of Innovation?
  - Is it customer focused?
  - Is there a sound quality system?
  - Will we have exclusivity?
  - Agility & Flexibility?
  - What is the approach to intellectual property?
  - Time taken to deliver translational research?

Key areas recommended for focus are:

- Enhancing ACvA's ability to operate as the one voice/one stop shop for discovery and innovation.

- Developing world's best practice platforms for nation-wide coordination of clinical trials (refer Anita van der Meers) with efficiencies in governance and operations, through working groups once established.
- Mapping current funding sources related to clinical research/trails and assess feasibility.
- Consultation with successful sectors re strategy- eg oncology.
- Supporting ongoing work for example, a major project being led by the George Institute, for the development of a register based on the Scottish model and suitable for the Australian context.
- Continuing efforts to develop and implement strategies for national big data solutions- maximizing use of routinely collected clinical and demographic data for efficiency in virtual registries, and embedded clinical trials.
- Building capacity in health economics/impact assessment and value-based care.
- Establishing effective and enduring industry/government partnerships to embed translation and commercialisation in the health system.
- Building off the ACvA flagship strategy and leadership, coordinating collaborative teams of expert researchers to provide "solutions" to health, industry and consumers- improving health impact, but also establishing an enduring CV research and translation industry/ecosystem.
- Prioritising the establishment of working groups – key vehicles to build trust and a shared understanding/language.
- Undertaking skills development, focussing on our emerging researchers – developing shared workstreams, webinars and workshop, industry and policy mentors.
- Developing and implementing strategy for coordinated engagement and promotion of Australian research capacity to global pharma/device/diagnostic industry research and translation leads.
- Connecting with Federal and State Industry Departments and advocating for investment in the CV research pipeline as commercially valuable strategy

Summary and Conclusions

- We have unprecedented support for industry/academic collaboration.
- The one stop shop platform provided by ACvA Flagships and membership is a significant asset to develop and mobilise further.
- Establishing working groups and ensuring the right people are on them (well networked, prepared to listen and prepared to roll up their sleeves) is critical.
- Identifying experienced champions for each Working Group is a priority.
- Developing strong consumer engagement initiatives is critical.

Next steps

- The Executive Director, ACvA to arrange one on one meetings with all industry invitees to collate input on priority workstreams and seek suggestions of key people to involve in working groups.
- Develop and circulate EOIs for working group membership, building on those who have nominated to date.
- Establish working Groups.
- Hold initial meetings:
    a. The core purpose is to develop and agree ToR and initial timeframes and deliverables.
    b. Seek offers of secretariat support from members (basic admin – arrange meetings, take action-oriented minutes, follow up on actions etc).

Attachments

A1. List of expected attendees
A2. Speaker bios
A3. Speaker slides
A4. Roundtable Program.

Appendix 1. List of expected attendees

First Name	Last name
Joshua	Ciardi
Grace	Wong
Keith	Broadfoot
Graham	Galloway
Falko	Thiele
Bill	Stavreski
David	Thomson
David	Mowbray
Ravinay	Bhindi
Martin	Baker
David	Abbott
Andrew	Soh
Steve	Worthley
Alta	Schutte
Ana	Svensson
Andrew	Eagling
Clare	Arnott
David	Sullivan
Jennifer	Byrne
John	Crothers
John	Fraser
Kerry	Anne-Rye
Kerry	Doyle
Kieran	O Brien
Martin	Ugander
Nicola	Ware
Salvatore	Mangiafico
Sarah	Benjes
Stephen	Nicholls
Kellie	Bourke
Jamie	Vandenberg
Garry	Jennings
Anna	Karelas
Robyn	Ward

Appendix 2. Speaker Bios

Dr Clare Arnott
Staff Specialist RPA
Women's Heart Centre, CPC
Cardiometabolic clinical trials George Institute
Postdoctoral Fellow HRI

Professor John Atherton
Royal Brisbane and Women's Hospital
Sits on the Metro North Heart Lung Executive.

John Crothers
Regional Director ANZ, Abbott Diagnostics
Chair Pathology Awareness, Australia

Rebecca Davies
Full time Non-Executive Director of Defence Health Ltd, The Actuator, Catholic Healthcare and more. Rebecca Davies AO is a former lawyer. She has been a member of NHMRC Principal Committees, including the Community and Consumer Advisory Committee and has been a consumer representative on multiple review panels and committees for NHMRC, MRFF, Sydney Health Partners and Sphere. Rebecca was formerly Chair of the Heart Foundation, NSW Division and on its national board. She is currently on the National Heart Foundation's strategic research committee and a member of the British Heart Foundation consumer panel for the Big Beat Challenge.

Professor Gemma Figtree
Professor, Sydney Medical School (Northern), Faculty of Medicine and Health
Interventional Cardiologist, Royal North Shore Hospital
Research Lead, Cardiothoracic and Vascular Health, Kolling Institute
Chair, Cardiovascular Initiative (University of Sydney DVCR)
President, Australian Cardiovascular Alliance
NHMRC Practitioner Fellow

Professor John Fraser
Chair of the Asia Pacific Extracorporeal Life Support Organisation
Professorships in Medicine, Anaesthesia, Critical Care and Engineering across five universities.
Chief Investigator of the First International Centre for Research Excellence in Mechanical Support (NHMRC).

Professor Stuart Grieve
Parker Hughes Chair of Radiology, Sydney Medical School.
Group Leader Cardiac Imaging, HRI

Professor Carol Pollock
Professor of Medicine.
Chair kidney health Australia.
Chair bureau health information.
Deputy chair National Organ, Tissue and Transplant Authority.
Member of NHMRC Council.

Professor Kerry-Anne Rye
Deputy Head of School (Research)
School of Medical Sciences
Faculty of Medicine

Kieran Schneemann
Director Government Relations AstraZeneca
Director Canteen

Anita van de Meer
Manager ClinicaltrialsNSW, Office of Health and Medical Research

Professor Andrew Wilson
Co-Director of The Australian Prevention Partnership Centre
Co-Director Menzies Centre
Chair PBAC

Appendix 3. Speaker Slides

ACvA Round Table – 17th of March - Program

Purpose
To build a strong platform of engagement between industry and the research community to tackle Australia's biggest health burden and drive economic outcomes.

1.30pm - Session one:
ACvA's Vision and Strategy- and the key role of our Industry Partners

- Welcome and overview of the day ***(Professor Kerry-Anne Rye)***
- ACvA initiatives and progress to date ***(Professor Gemma Figtree)***
- A shared vision - best CV health for Australians underpinned by a thriving impactful research and innovation sector ***(Professor Kerry-Anne Rye)***

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The Australian Cardiovascular Alliance, and the Mission

Gemma Figtree

- The health and societal burden of Cardiovascular (CV) disease is a looming tsunami.
- The ACvA is uniquely positioned to leverage key interactions between our strong national research capability and the health system to improve health outcomes and reduce costs.
- ACvA successfully advocated for federal investment in the **Mission for Cardiovascular Health- $220 Mill**, but this is just the beginning
- *Strategic investment and coordinated leadership through the ACvA* will build whole of nation pipelines to transform discoveries for the clinic, and to build a valuable industry embedded in this sector.
- Our goals :
  1. Increase capacity by reversing the brain drain of CV specialists;
  2. Accelerate discovery of more effective, personalised treatments;
  3. Enhance translation and attract investment; and
  4. Improve the health of Australians.

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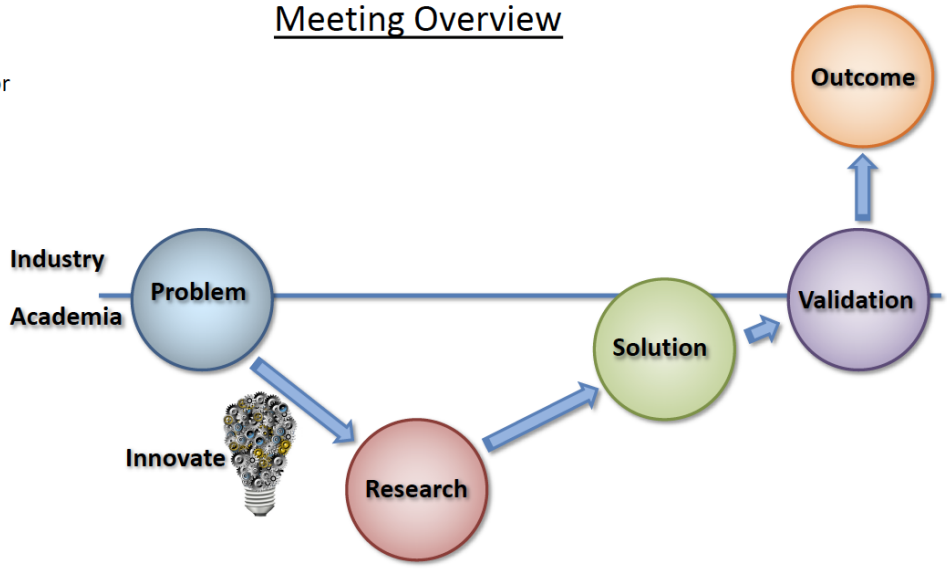
ACvA Round Table – 17th of March

Kerry-Anne Rye

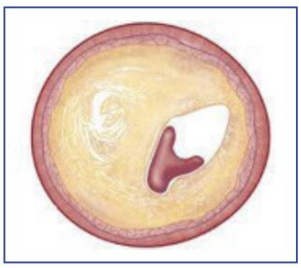
- Deliver optimal CV health for all Australians
- Role of partnerships
- Discussion
  - Vision
  - Define priorities
  - Develop strategies

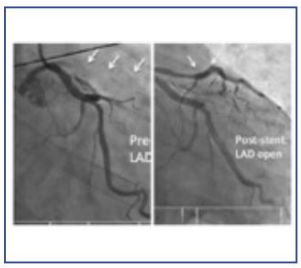
Meeting Overview



Major gaps: delivery, translation, and missing biology

	Perception that CV disease is all solved, with stigma that heart attacks and strokes are self-induced through unhealthy lifestyles
	Over 1 million Australians aged 45-74 years have >15% absolute risk of CV event in the next 5 years and are not receiving best preventative care
	Valley of death: coordinated strategy required for translation and commercialisation of Australian discovery
	Pathobiology of heart disease is not all solved, with up to 27% of heart attack patients (like Scott; right) having no standard modifiable risk factors
	Precision Medicine: need coordinated effort to identify mechanisms of individual susceptibility or resilience, the key to new markers and personalised treatments





Scott Kesteven, one of approximately 10,000 Australians who suffer a heart attack despite a "clean bill of health" and no traditional modifiable risk factors

Proposed model: Strategic Flagships supported by Capacity Building Initiatives

Six Strategic Flagships

Drug Discovery	Bioengineering	Precision Medicine	Big Data	Clinical Trials	Implementation and Policy
Promoting targeted development of new therapies incorporating emerging biology	*Accelerating the development and translation of devices, tissue engineering, and advanced CV imaging*	*Embedding multi-omic platforms and computational bioinformatics with well-phenotyped clinical cohorts to discover new markers and mechanisms*	*Leveraging emerging opportunities in data science applied to national coordinated cohort studies, registries and electronic medical records to open new frontiers*	*Including rigorous testing of Australian discoveries and devices, and drug repurposing, as well as innovations in delivery of care*	*To deliver best CV care for all Australians, from prevention and primary care through to the interventional catheter laboratory and operating theatre*

Capacity building initiatives supporting all Flagships:

National CV Bioinformatics Institute
Australian CV Commercialisation Hub
Indigenous CBI
Clinician Researcher Catalyst Awards Scheme
AHRTC and Primary Care Catalyst Grants
Advanced Cardiovascular Imaging
National Leadership/mentorship Programs; International and National Conferences; CV Ambassador Awards

MRFF PRIORITY FUNDING: $20 million per annum to fund an integrated, whole-of-nation strategy addressing Australia's most pressing health burden

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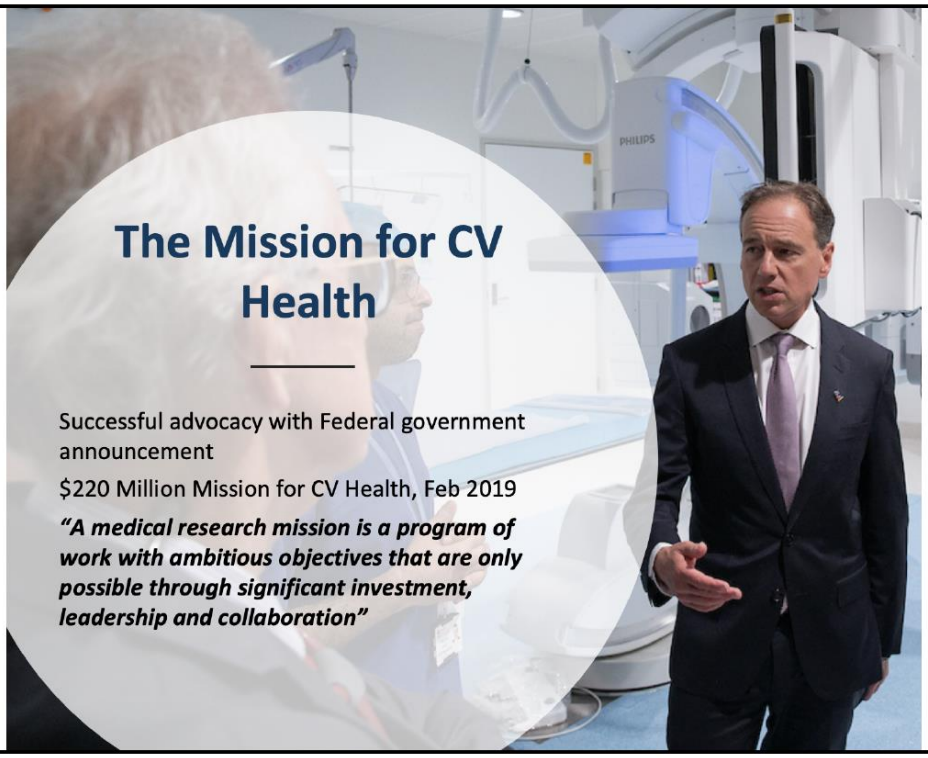


Roadmap- for Ministerial endorsement

Vision

Transformative improvements in heart and vascular health and stroke for all Australians.

Mission statement

The Mission will accelerate Australian-led research to advance cardiovascular health, through the creation of a world-class sustainable ecosystem that serves the health system, underpinned by strategic investment, excellence, collaboration, innovation, consumer engagement and commercialisation.

Investment Flagships

Funding for heart, vascular, and stroke research will be invested across strategic interrelated and complementary Flagships:

Drug discovery

- Targeted development of new therapies incorporating emerging biology.

Bioengineering

- Development, implementation and translation of bioengineering approaches for cardiovascular health to improve diagnosis, precision treatment and outcomes using bio devices, 3D tissue engineered products, and application of bioengineering models to maximise data utilisation and prediction.

Precision medicine

- Embedding multi-omic platforms and computational bioinformatics within well-characterised clinical cohorts to discover new markers for early disease detection and identify mechanisms to provide evidence-based targeted and tailored treatment.

Big Data

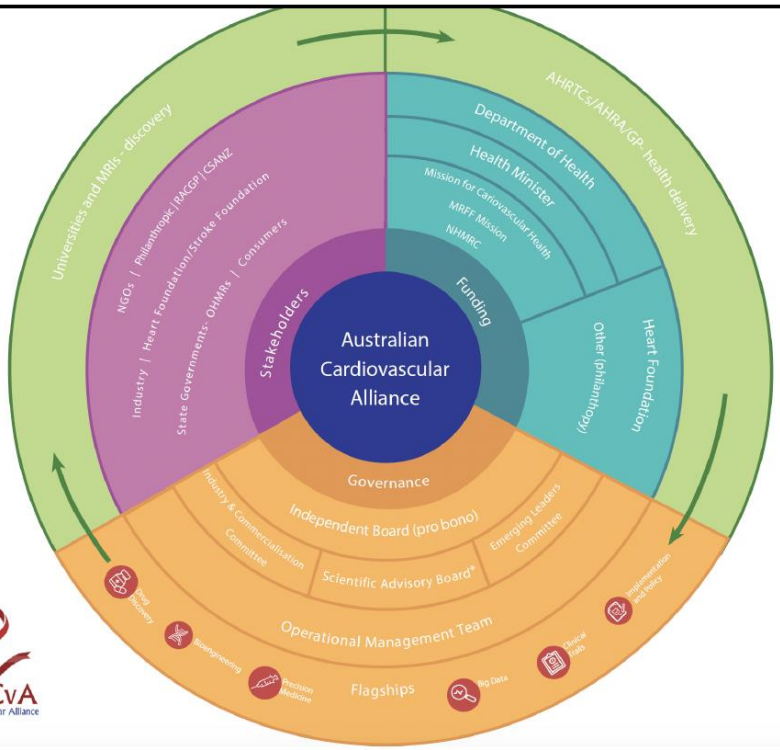
- Utilise and optimise large-scale data to support efficient, innovative research, improving the health system and health outcomes.

Clinical trials

- Rigorous testing of innovative interventions in primary care, acute care, rehabilitation and community settings.

Implementation and policy

- Research focussed on implementing effective and efficient prevention and care, including supporting evidence-informed clinical and policy decision making.



Making the most of the Mission $:

- Leverage
- Networks and collaboration
- Industry
- Embedding in health care

$1.5 Mill Operational Platform
Exec Director
Program Managers
Flagship Directors and AG

ACvA
Australian Cardiovascular Alliance

Industry and Commercialisation

Professor Kerry Ann Rye

Mr Ben Wright

Opportunities for building an academic–industry partnership and optimising Australians access to evidence-based care

- Multi-disciplinary team approach
- Cross-sector workforce training (industry and academia)
- Establishing a "front door" for global industry and venture capital to access and engage with Australian cardiovascular innovation and discovery
- Firmly placing Australia as the global destination for clinical trials
- Improve patient awareness surrounding de-identified data being captured for research in order to improve patient outcomes
- Unlock and use government held health data to measure outcomes
- Link patient outcomes to health economics to drive policy and decision making
- Repurposing (investigation of existing drugs for new therapeutic purposes)
- Accessibility to highly functional clinical trial tools
- Creation of flexible and fluid career opportunities permitting movement between academia and industry without career progression penalties

ACvA in 2020 and beyond

How can we continue to build on the ACvA platform and help you?

Executive Director and Flagships

Collaborative platform embedded in health system and increasing industry

More sustainable career pathways, mentorship

Continuing engagement with Federal government, MRFF and NHMRC

Expand advocacy and interaction with States

Deepen industry partnerships

Improved engagement with Institutes and Societies

Build pipeline to implementation and policy

Measuring impact- health and economic

Community and government messaging- work with others towards common message

Big data and bioinformatics capacity

Annual Awards night

Build on trust within sector- the benefits of a national platform and one voice

BIOPLATFORMS AUSTRALIA

NSW Health

THE SNOW FOUNDATION

Heart Foundation

ACvA Round Table – 17th of March

1.40pm -2:10pm – Session two:

Accelerating delivery of evidence-based and value-based care for optimal CV health for all Australians

- Consumer perspective ***(Ms Rebecca Davies AO) and Mr Kieran Schneemann***
- Government and PBAC perspective ***(Professor Andrew Wilson) TBC***
- MSAC and clinical cardiology perspective ***(Associate Professor John Atherton)***
- Challenges in Pharma ***(Professor Carol Pollock)***

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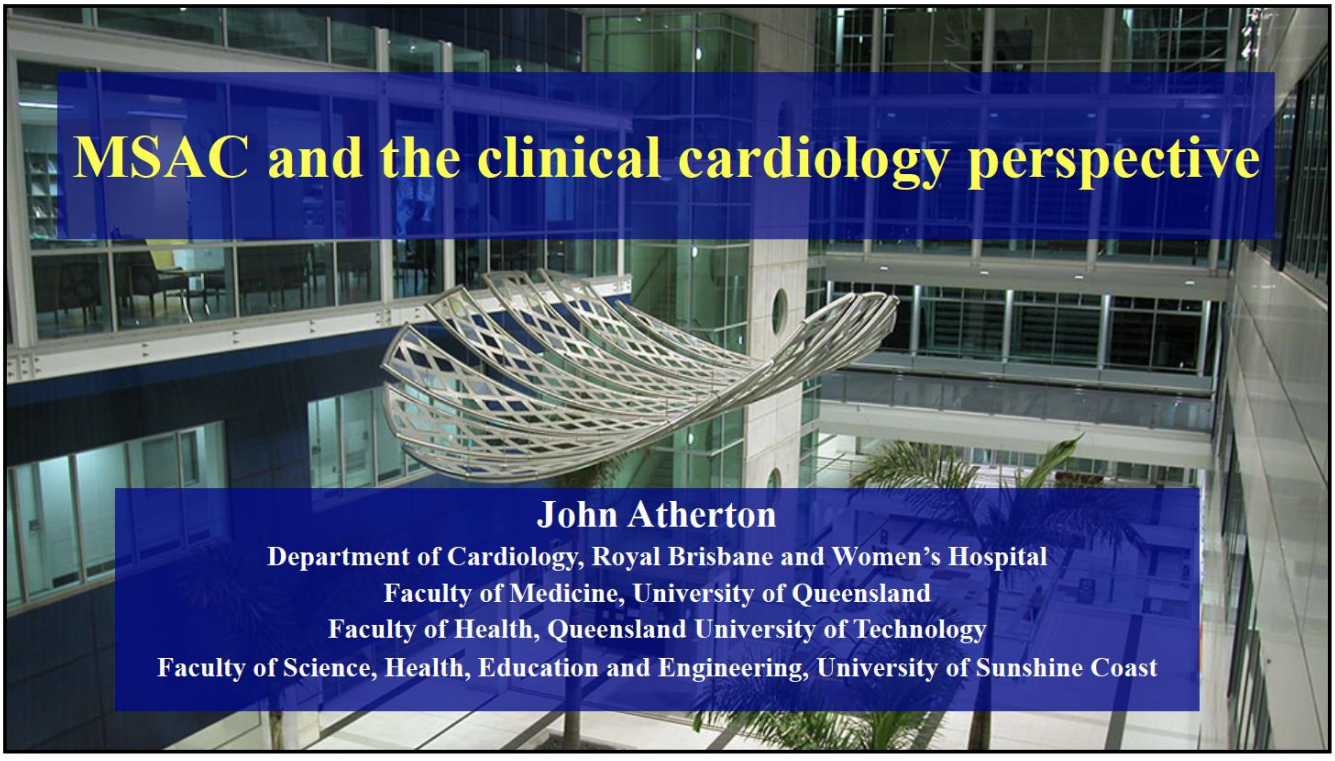


What is the MSAC?

The Medical Services Advisory Committee (MSAC) is an independent non-statutory committee established by the Australian Government Minister for Health in 1998.
MSAC appraises new medical services proposed for public funding, and provides advice to Government on whether a new medical service should be publicly funded (and if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness and total cost, using the best available evidence.
Amendments and reviews of existing services funded on the Medicare Benefits Schedule (MBS) or other programmes (for example, blood products or screening programmes) are also considered by MSAC.
While most applicants to MSAC are seeking reimbursement under the MBS, MSAC is not restricted to providing advice around MBS funding. MSAC also promotes advice in regards to non MBS funding where relevant.
The MSAC also advises the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.

What is the MSAC?

The MSAC is supported by two sub-committees, the PICO Advisory Sub-committee (PASC) and the Evaluation Sub-committee (ESC). MSAC and its sub-committees are further supported by clinical experts and Health Technology Assessment (HTA) Groups who provide a range of assessment, review and research support services to the Department.
MSAC is a ministerially appointed committee with membership periods that are staggered to reduce operational impact for future changes. MSAC and its sub-committees are comprised of members from a wide range of clinical disciplines and from fields of health that include health economics, evidence based health care, health policy, and consumers. Members may serve on MSAC, and/or any of its sub-committees. As MSAC is a non-statutory committee, there is no obligation on Government to accept or implement the advice MSAC provides.

Application process to the MSAC?

To apply for public funding Applicants are required to provide a completed application form which, among other things, confirms lobbyist status and requests the Applicant provide a letter of support from an associated professional body/organisation and consumer group.
Applications can be made by the medical profession, medical industry and others with an interest in seeking Australian government funding for a new medical service or change to an existing service.
When submitting an application form, the applicant is required to identify key journals or research published (or yet to be published) in relation to the proposed medical service, as well as provide a statement of clinical relevance for the proposed medical service from those professional body/organisation(s) representing the group(s) of health professionals who provide the service and a letter of support from a relevant consumer organisation.
Department will assess the application to determine its suitability to proceed through the Medical Services Advisory Committee (MSAC) process.

Key steps for the MSAC process?

Pre-assessment stage
Aprrox. 20 weeks

Triage: Department verifies the availability of evidence, determination of suitability for MSAC consideration and discussion of what would be the most efficient pathway to progress the application. Targeted public consultation.
Population Intervention Comparator Outcome (PICO) Confirmation: PICO Confirmation is developed by a HTA Group including clinical algorithms. The applicant, department and PASC aim to have an agreed PICO to undertake a systematic review and generate an economic model.
Application Assessment: Evidence outlined in the PICO confirmation is presented in an Assessment report.

Assessment stage
Approx. 22 weeks

Assessment report is reviewed by ESC to identify the gaps and level of uncertainty in the evidence.
Appraisal: MSAC appraises the evidence before advising Government. MSAC consideration includes the assessment report, the independent critique, the ESC report, feedback from the applicant/ other relevant parties, and the individual expertise of MSAC members.
MSAC's advice to the Minister is made public on the MSAC website via a Public Summary Document.

MSAC Advice and post-MSAC process

MSAC deliberations result in a recommendation to either:

- Support funding
- Not support funding
- Defer consideration

The Applicant provided the option for a post MSAC debrief with the department.
New policy proposals developed by the department include liaison with applicant/clinical experts.
Department advises Minister on MSAC deliberations and seek authority to put forward the new policy proposals through the Budget process.
Budget brought down by the Treasurer on the second Tuesday of May each year.
Government decide on public funding based on MSAC/ Department advice.
Once approved, department implement decision through amendment to regulations and/or other instruments for the listing of the recommended service on the MBS.

Predicted versus Actual Utilisation Monitoring

The Department reports to MSAC on the utilisation of MBS items to ensure new items or item amendments are being used as intended.
Assesses the real-world impacts of MSAC-supported applications by comparing projections of claims with actual service volume patterns 24 months after listing.

MSAC can make recommendations in relation to:
referring inappropriate co-claiming to the Department compliance area;
the MBS item descriptor and fee for the `service requiring amendment;
identifying issues with access to services;
other matters related to the public funding of health services.

Post-MSAC process (cont.)

Co-dependent technologies:
Co-dependent technologies are medical technologies that rely on another technology to achieve its intended purpose or enhance its effect.
Co-dependent technologies usually require advice to the Minister from two different expert advisory committees because listing needs to occur under two separate funding programs (e.g. PBS and MBS, or MBS and Prostheses List).
Listing of a prosthesis/ device:
Some MSAC applications are for services that will use an implantable medical device that may meet the criteria to be listed on the Prostheses List.
The Prostheses List Advisory Committee provides advice to the Government about the listing of devices on the Prostheses List and the benefits that should apply.
Sponsors may make applications to list devices on the Prostheses List at the same time as the associated service is considered by MSAC.
Devices will not be listed on the Prostheses List until an item for the associated service is included on the MBS.
Medical Research Future Fund submissions

MSAC: Cardiology considerations

Rapidly evolving evidence
Large burden of disease
Processes to support applications to MSAC
Ensuring research informs health policy
- Formulating research question
- Clinical trial design
- Capturing health outcomes to inform economic models

Ensuring safe, effective, cost-effective and equitable implementation of new evidence (e.g. national cardiac procedures registry)

ACvA Round Table – 17th of March

Professor Carol Pollock Industry and academic partnerships

- Be aware of Industry pipelines, interests, grant programmes
- Take opportunity to visit company scientists
- Be clear on expectations of both partners
- Respect each others skill base
- Timelines and outputs may differ between industry and partner
- Local biotechs/ SMEs may be more amenable to partnering
- Ownership of Intellectual Property not the 'be all and end all'
- Tech transfer offices in the university should prioritise flexibility
- Be aware of opportunities to leverage funds eg NHMRC Partnership grants, ARC Linkage funding; joint student scholarships, BTB (Biomedical Translation Bridge – from MRFF funding and powered by MTP Connect)
- Develop embedded relationships

ACvA Round Table – 17th of March

2:10pm - 2:40pm - – Session three

A new vision for Australian CV industry/academic partnerships

- State Government representative ***(Ms Anita Van Der Meer)*** - Health and economic drivers for building sustainable industry academic partnerships in the CV space
- Australia as the "go to" destination for large scale clinical trials ***(Dr Clare Arnott)***
- Building a national showcase and "one front door" to facilitate industry engagement at early stages of discovery and innovation ***(Professor John Fraser)***
- Industry/academic partnerships in advancing CV imaging- who does it well and opportunities in Australia ***(Professor Stuart Grieve)***
- Promoting the ACvA and the Australian CV research sector to our global research leads - working together to build a world-leading translational research eco-system ***(Mr John Crothers- Abbott)***

2:40pm-3pm – **Working group nominations and next steps**

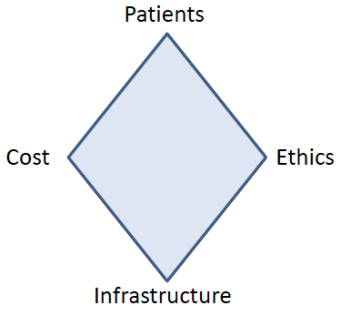
Ms Anita Van Der Meer)

ACvA Round Table – 17th of March

ACvA
Australian Cardiovascular Alliance

Clare Arnott **Australia as the "go to" destination for large scale clinical trials**

- **KEY ISSUES**
  - Poor patient recruitment particularly in general practice
  - Significant time delays due to lack of existing infrastructure, lack of established networks, difficult ethics systems
  - High cost and low yield for industry to invest in
- **SOLUTIONS**
  - Nation-wide, disease agnostic registry within the community to facilitate rapid recruitment
  - Creation of a network of personnel with the ability to mobilise immediately across sites
  - Close dialogue with industry to understand mutual needs



ACvA Round Table – 17th of March

Stuart Grieve Industry/academic partnerships in advancing CV imaging

Who does it well? Opportunities in Australia…

- Strong local presence from Siemens and more recently GE and Philips
- Support is scattered and primarily "vendor to group" with some significant institutional relationships
- The "main game" is probably not equipment… but data and novel clinical use of new measures
- Non-"vendors" also are and will become more important eg. private radiology and medical provideres
- Challenges revolve around deploying capability due to lack of expertise on the ground

Partnering to Improve CAD Globally

John Crothers
Abbott, Director

The Purpose of this presentation is to consider….

Promoting the ACvA and the Australian CV research sector to our global research leads - working together to build a world-leading translational research eco-system

- Healthcare MNC perspective – Focus on Diagnostics
- Current and future opportunities and approaches to partnering in research and development

Abbott at a glance

107,000 PEOPLE

130+ YEARS IN BUSINESS

160+ COUNTRIES

$31.9B 2019 SALES

TRUSTED PRODUCTS

FreeStyle Libre, MitraClip, Similac, Alinity, Ensure, ID NOW, Pedialyte, BurstDR, Xience, BRUFEN

Products may not be available in all markets

Abbott Overview

Is there opportunity to improve Australia's position with MNC investment

Issue: Geography, time zone and relationships

How: Create a value proposition they can't refuse. Do it in collaboration – not on your own. "**Power of One**" (ACvA). Your competition is not down the road, but in another country/region.

Who: Work with local contact to champion **value proposition**.

New opportunity partnership assessment timeframes are defined by their complexity

- Global Business Development approached or search for opportunity.
- Opportunity aligns to strategic imperative of Division and pipeline focus.
- Business case developed and project traded-off versus other opportunities.
- Executive decision made.
- Contracts agreed.
- Project executed.

Key partner criteria assessment Abbott considers…..

Strategically Aligned

Quality system

Exclusivity

Balanced

Innovation

Intellectual Property

Agile

Flexibility

Pedigree

Creativity

Customer Focused

Timing

What next for ACvA?

Issue: How to best promote the ACvA and the Australian CV research sector to our global research leads - working together to build a world-leading translational research eco-system

How: Utilise a framework – i.e. GROW. Facilitated workshop with the right people engaged to establish our value proposition that meet requirements of success & way-forward

Who: Passionate volunteers wanted!

Appendix 4. Roundtable Program

Venue
Virtual ACvA Industry Roundtable

Time
1:30pm-3pm

Purpose
To build a strong platform of engagement between industry and the research community to tackle Australia's biggest health burden and drive economic outcomes.

Program
1.30pm - Session one:
ACvA's Vision and Strategy- and the key role of our Industry Partners

- Welcome and overview of the day ***(Professor Kerry-Anne Rye)***
- ACvA initiatives and progress to date ***(Professor Gemma Figtree)***
- A shared vision - best CV health for Australians underpinned by a thriving impactful research and innovation sector ***(Professor Kerry-Anne Rye)***

1.40pm -2:10pm – Session two:
Accelerating delivery of evidence-based and value-based care for optimal CV health for all Australians

- Consumer perspective ***(Ms Rebecca Davies AO and Mr Kieran Schneemann)***
- Government and PBAC perspective ***(Professor Andrew Wilson)***
- MSAC and clinical cardiology perspective ***(Associate Professor John Atherton)***
- Challenges in Pharma ***(Professor Carol Pollock)***

2:10pm - 2:40pm – Session three
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2:40pm-3pm – **Working group nominations and next steps**